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FACSIMILE TRANSMISSION  
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TO : EXAMINER MICHELE FLOOD, ART UNIT: 1654

COMPANY : UNITED STATES PATENT AND TRADEMARK OFFICE

FAX NO. : 703-872-9307

FROM : ALBERT WAI-KIT CHAN

DOCKET : SHEN, et al., for COMPOSITION COMPRISING  
EXTRACTS OF FLOS LONICERAE, FRUCTUS  
FORSYTHIZE AND RADIX SCUTELARIAE, USES AND  
PREPARATION THEREOF, U.S. Serial No. 10/032,514,  
Filed October 24, 2001, claiming priority of Chinese Patent  
Application No. 00125764.1, Filed on October 25, 2000 - Dkt.  
#735-US

TOTAL NUMBER OF PAGES, INCLUDING COVER SHEET : 12

DATE : October 8, 2003

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Message

Applicants: SHEN, et al.  
Client: National Engineering Research Center for Traditional Chinese Medicine  
File No.: 735-US  
Date: October 8, 2003

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT** for SHEN, et al. for COMPOSITION COMPRISING EXTRACTS OF FLOS LONICERAE, FRUCTUS FORSYTHIZE AND RADIX SCUTELARIAE, USES AND PREPARATION THEREOF, U.S. Serial No. 10/032,514, Filed October 24, 2001, claiming priority of Chinese Patent Application No. 00125764.1, filed on October 25, 2000.

THE INFORMATION CONTAINED IN THIS FACSIMILE TRANSMISSION IS INTENDED SOLELY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENT(S) NAMED ABOVE. THIS TRANSMISSION MAY CONTAIN INFORMATION THAT IS CONFIDENTIAL UNDER THE CLIENT AND ATTORNEY RELATIONSHIP. IF THE READER OF THIS MESSAGE IS NOT A DESIGNATED RECIPIENT OR AN AGENT RESPONSIBLE FOR DELIVERING IT TO A DESIGNATED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISTRIBUTION, OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR OR IF UPON READING THIS DOCUMENT YOU HAVE REASON TO BELIEVE THAT THE DOCUMENT WAS INADVERTENTLY SENT TO YOU, PLEASE NOTIFY US IMMEDIATELY BY COLLECT TELEPHONE CALL AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.

Dkt. #735-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : SHEN, et al.  
U.S. Serial No.: 10/032,514 Examiner: Michele Flood  
Filed : October 24, 2001 Art Unit: 1654  
For : COMPOSITION COMPRISING EXTRACTS OF FLOS  
LONICERAE, FRUCTUS FORSYTHIAE AND RADIX  
SCUTELLARIAE, USES AND PREPARATION THEREOF

Law Offices of Albert Wai-Kit Chan, LLC  
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Whitestone, New York 11357

October 8, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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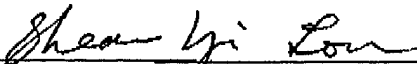
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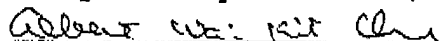
Sir/Madam:

FACSIMILE CERTIFICATE  
IN CONNECTION WITH THE ABOVE-IDENTIFIED APPLICATION

I hereby certify that this paper is being sent on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Printed Name: Sheau Yi Lou

Respectfully submitted,

  
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Dkt. #735-US

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October 8, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following reference which is listed on Form PTO/SB/08A (Exhibit A) and is attached hereto as Exhibit 1.

1. The 17 September 2003 PCT Written Opinion issued from International Preliminary Examining Authority.

Applicants : SHEN, et al.  
U.S. Serial No.: 10/032,514  
Filed : October 24, 2001  
Page : 2

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of these Amendments. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan

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OCT-08-2003 15:58 FROM:LAW OFFICES-A.CHAN 7183578615

TO:

P.005/012

# **Exhibit A**



OCT-08-2003 15:59 FROM: LAW OFFICES-A.CHAN 7183578615

TO:

P.007/012

# Exhibit 1

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
ALBERT WAI-KIT CHAN  
LAW OFFICES OF ALBERT WAI-KIT CHAN, LLC  
WORLD PLAZA, SUITE 604  
141-07 20TH AVENUE  
WHITESTONE, NEW YORK 11357

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference		Date of Mailing (day/month/year)	<b>17 SEP 2003</b>
1053-A-PCT		REPLY DUE	within 1 months/days from the above date of mailing
International application No.	International filing date (day/month/year)	Priority date (day/month/year)	
PCT/US01/50424	24 October 2001 (24.10.2001)	25 October 2000 (25.10.2000)	
International Patent Classification (IPC) or both national classification and IPC			
IPC(7): A61K 35/78 and US Cl.: 424/725, 741, 773, 777, 778			
Applicant			
NATIONAL ENGINEERING RESEARCH CENTER FOR TRADITIONAL CHINESE MEDICINE			

- This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - ☒ Basis of the opinion
  - ☐ Priority
  - ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☐ Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.
 

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

**If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 25 February 2003 (25.02.2003).

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer <i>Christopher R. Tate</i> Christopher R. Tate Telephone No. 703-308-0196
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Form PCT/IPEA/408 (cover sheet)(July 1998)



## WRITTEN OPINION

International application No.

PCT/US01/50424

## I. Basis of the opinion

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages 1-93, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 94-104, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-7, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

Form PCT/IPEA/403 (Box I) (July 1998)

## WRITTEN OPINION

International application No.

PCT/US01/50424

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 4-8 and 15-24

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 4-8 and 15-24.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Form PCT/IPEA/408 (Box III) (July 1998)

## WRITTEN OPINION

International application No.  
PCT/US01/50424**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims 9-14, 25, 26 and 29	YES
	Claims 1-3, 25, 27, 28 and 30-32	NO
Inventive Step (IS)	Claims 12 and 13	YES
	Claims 1-3, 9-11, 14 and 25-32	NO
Industrial Applicability (IA)	Claims 1-3, 9-14 and 25-32	YES
	Claims NONE	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3, 25, 27, 28, and 30-32 lack novelty under PCT Article 33(2) as being anticipated by Xu.

Xu teaches antibacterial, antiviral pharmaceutical compositions comprising Flos Lonicerae, Fructus Forsythiae, and Radix Scutellariae within the claimed amounts/ratios (see entire document).

Claims 1, 2, and 30-32 lack novelty under PCT Article 33(2) as being anticipated by Li.

Li teaches an antibacterial, antiviral pharmaceutical composition comprising Flos Lonicerae, Fructus Forsythiae, and Radix Scutellariae (see abstract).

Claims 1-3, 9-11, 14, and 25-32 lack inventive step under PCT Article 33(3) as being obvious over Xu and Li in view of Moyler.

Xu and Li teach antibacterial, antiviral pharmaceutical compositions comprising Flos Lonicerae, Fructus Forsythiae, and Radix Scutellariae. Xu further teaches these herbal agents within the claimed amounts/ratios (as discussed above).

Moyler beneficially teaches that supercritical CO<sub>2</sub> fluid extraction, including in conjunction with an alcoholic entrainer, is an effective and environmentally friendly method of preparing herbal plant extracts from various parts of plants (for example, fruits, roots, buds, etc.) - see entire document.

It would have been obvious to utilize supercritical CO<sub>2</sub> fluid extraction to efficiently (and without harming the environment) prepare the antibacterial, antiviral plant extracts taught by Xu and Li based upon the beneficial teachings provided by Moyler. The result-effective adjustment of conventional working parameters (for example: pressure, temperature, and/or time used during such CO<sub>2</sub> supercritical fluid extraction) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 12 and 13 meet the criteria under PCT Article 33(2)-(3), because the prior art does not teach nor reasonably suggest a method for preparing the claimed herbal agents via further including the step of embedding the supercritical extract with a saturated solution of beta-cyclodextrin as claimed.

Claims 1-3, 9-14, and 25-32 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter can be made or used in industry.

Form PCT/IPEA/408 (Box V) (July 1998)

**WRITTEN OPINION**

International application No.  
PCT/US01/50424

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

Form PCT/IPEA/408 (Supplemental Box) (July 1998)